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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/491,322

Applicant(s)

HEIN ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 06 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 13,15-27 and 29-91 is/are pending in the application.
- 4a) Of the above claim(s) 66-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 13,15-27, 29-65, 83-91 is/are rejected.
- 7) ☐ Claim(s) 83 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on February 13, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/491322 is acceptable and a CPA has been established. An action on the CPA follows.

The Amendments filed March 14, 2002 and May 30, 2002, paper nos.15 and 18, have been entered.

Claim 28 is cancelled.

Claims 13, 18, 19, 22-24, 29, 30, 41 and 66 are newly amended.

Claims 31 to 91 are newly added.

Claims 13, 15-27 and 29-91 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 13, 15-27, 29-65 and 83-91 directed to a method of passively immunizing a human or non-human animal subject by administering a formulation comprising a dual chain immunoglobulin molecule, in Paper No. 20 is acknowledged. The traversal is on the ground(s) that a search and examination of all groups would not be unduly burdensome as all the groups are directed to antibodies expressed in plants, and because the application claims priority to prior cases directed to the same art. This is not

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found persuasive because the Groups are directed to different types of antibodies as well as to different types of methods. While the searches of the four groups of invention may overlap with each other as well as with the prior cases to which the instant application claims priority, their searches are not coextensive. Accordingly, claims 66-82 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claim 83 is objected to because it recites a nonelected invention. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29-30, 48-50 and 86-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a nucleotide sequence encoding an immunoglobulin heavy chain comprising "at least a portion" of a constant region. The recitation of "at least a portion" of a constant region introduces new subject matter not properly described in the application as filed.

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The recitation of "at least a portion" of a constant region encompasses polypeptides having as few as one amino acid to as much as one amino acid less than a full-length polypeptide, yet the original disclosure references antibody fragments that would have been interpreted by one of skill in the art to cover only specific antibody fragments that were known in the art, such as Fab, Fab', F(ab')<sub>2</sub> and Fv, not antibody fragments comprising any polypeptide from a single amino acid to one amino acid less than the full length polypeptide. Accordingly, the recitation of "at least a portion" of a constant region is considered an introduction of new subject matter not properly described in the application as filed.

***Claim Rejections - 35 USC § 102***

Claims 13, 15-27, 29-65 and 83-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolle et al. (US Patent No. 4,748,018), for the reasons of record set forth in the office action mailed August 13, 2001.

Applicant's arguments filed March 14, 2002 and May 30, 2002 have been fully considered but they are not persuasive.

Applicants argue that Stolle et al. fails to anticipate the claims as a matter of law because Stolle et al. do not teach that the immunoglobulin which is used for passive immunization be obtained from transgenic plant cells, that the nucleic acid encode a leader sequence, or that the leader sequence form a secretion signal which is cleaved from the immunoglobulin polypeptide following proteolytic processing (reply March 14, 2002 page 10). Applicants further argue that a composition comprising an immunoglobulin derived from mammalian cells taught by Stolle et al. would contain viral or proviral proteins or other contaminants that necessarily are absent from

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the plant derived immunoglobulin as taught by Applicants. Additionally, Applicants argue that glycoprotein contaminants in plant derived immunoglobulins would not contain sialic acid while glycoprotein contaminants in mammalian derived immunoglobulins would contain sialic acid (reply May 30, 2002 page 5).

That Applicants' antibodies are produced in plants does not in itself distinguish the instant method from the method taught by Stolle et al. Applicants have not shown that their antibodies, by their production in plants, are structurally different from the antibodies used by Stolle et al. With respect to Applicants' arguments regarding viral contaminants, the Office notes that absent viral infection of the cells, a composition comprising an immunoglobulin derived from mammalian cells would not contain viral or proviral proteins or other contaminants. Furthermore, the Office notes that plant cells are also susceptible to infection by viruses. With respect to Applicants' argument regarding sialic acid glycoprotein contaminants, the previous Office actions indicated that the antibodies of Stolle et al. are inherently free of sialic residues absent evidence to the contrary.

### ***Claim Rejections - 35 USC § 103***

Claims 13, 15-27 and 29-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (US Patent No. 4,956,282) and the During dissertation (Univ. of Koln, FRG, English translation, July 9, 1988) in view of Stolle et al. (US Patent No. 4,748,018), for the reasons of record set forth in the office action mailed August 13, 2001.

Applicant's arguments filed March 14, 2002 and May 30, 2002 have been fully considered but they are not persuasive.

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Applicants argue that During fails to teach or suggest transgenic plant cells containing a nucleic acid encoding an immunoglobulin, an antigen-specific immunoglobulin product encoded by the nucleic acid, a leader sequence that forms a secretion signal that is cleaved from the immunoglobulin polypeptide, isolation of the immunoglobulin from the plants cells and administration of immunoglobulin in an amount appropriate for passive immunization. Applicants argue that During used an expression strategy different from that of Applicants and that During does not teach the claim requirement for proteolytic processing of a leader sequence and assembly of heavy and light chains to form an antigen specific immunoglobulin in the plant cell (reply March 14, 2002 pages 12-13).

First, the Office again notes that the claims are directed to a method of passive immunization, and that Applicants have provided no evidence which definitively shows that the antibodies produced in plants cells and used in Applicants' methods are structurally different from the antibodies of the prior art. Second, the Office again notes that only claims 29 and 30 require that the immunoglobulin be a complete and fully assembled molecule. Since many of Applicants objections to during are directed to the issue of the technical difficulty of producing fully assembled antibodies in plant cells, the objections are not commensurate in scope with the claims, as Applicants' immunoglobulin molecule reads on fragments of the fully assembled molecule.

Applicants also argue that During's assertion of successful antibody expression in plants would not have been believed by one skilled in the art, and the During dissertation is non-enabling. Applicants argue that at the time of their invention there was a prejudice in the art

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against the use of plant cells for the production of antigen specific immunoglobulins, and Applicants point to the submitted declaration of Lerner in support of this argument (reply March 14, 2002 pages 13-15). Applicants additionally argue that During's results are internally inconsistent and lack critical controls, and Applicants point again to the submitted declaration of Lerner in support of this argument (reply March 14, 2002 pages 15-19).

Regarding the assertion of prejudice in the art against the possibility of using plant cells to process and assemble an antigen specific immunoglobulin, the Office notes that the rejected claims are not directed to processed and fully assembled antigen specific immunoglobulins. Regarding the assertion that During's experimental results are internally consistent and lack critical controls, Applicant's arguments and the Lerner declaration are primarily directed to the production of processed and fully assembled antigen specific immunoglobulins molecules in plants, and thus are not commensurate in scope with the claimed invention.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.




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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
November 13, 2002

  
PHUONG T. BUI  
PRIMARY EXAMINER

11/13/02